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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
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| 10 054,419 | 01 22 2002 | Linda S. Powers | 13368.0002 | 5178 |

7590 04 22 2003
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EXAMINER

SAUCIER, SANDRA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 04 22 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/054,419

Applicant(s)
Powers et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 a. In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704 b.

Status

- 1) ☒ Responsive to communication(s) filed on Feb 11, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above, claim(s) 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, and 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 22, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited PTO-892 | 4) <input type="checkbox"/> Interview Summary PTO-413; Paper No. s. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review PTO-948 | 5) <input type="checkbox"/> Notice of Informal Patent Application PTO-152 |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement s PTO-1449 Paper No. s <u>1</u> | 6) <input type="checkbox"/> Other _____ |

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DETAILED ACTION

Claims 1-27 are pending. Claims 1-13, 15, 17-27 are considered on the merits. Claims 14, 16 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 14 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Applicant's election of Group I in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The disclosure is objected to because of the following informalities: "porphyrins" has been misspelled on page 7, last line.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1-13, 15, 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 17 and 19 are indefinite because in step a, it recites "exciting at least one intrinsic microbial fluorophore *having a specific range of electromagnetic radiation wavelength above 200 nm*". It is unclear if this refers to the excitation wavelength or the emission wavelength.

The independent claims 1, 8, 17, 19, 23 use the term reflected/scattered excitation energies. It is unclear what the slash means between reflected and scattered. Are these terms interchangeable or are they distinct kinds of energies that are determined independently?

Claims 1 and 8 have passive language in step c or d respectively "whereby the enumeration of microbes *is determined* by etc.. Please use active

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language in method claims. For example, "determining the number of microbes etc.".

Claim 1 appears to be incomplete as the preamble only mentions detection of the microbes, not quantification (enumeration).

Step c in claim 1 lacks clarity because it appears from the specification that the enumeration of the microbes is correlated to the detected fluorescence minus the reflected/scattered energies and minus the background energies. However, the manner in which the claim is phrased does not properly reflect this critical element.

Claim 2 lacks precedent for the recitation of "the relative ratios of multiple detected, background-corrected signals etc.". Thus, the reference to the independent claim is unclear.

Claim 3 misspells "fluorophore" and "dipicolinate".

Claims 5, 11 and 12 misspell "protozoa".

Claim 8 lacks clarity because in step d, it recites "whereby the enumeration...is determined by the magnitude of the detected signal", where it is the detected signal minus the reflected/scattered energies and background values, that is correlated with number of microbes.

Claim 10 misspells "dipicolinate".

Claim 17 is indefinite because in step c, the amount of toxin is determined by the magnitude of the fluorescence signals minus the background and the reflected/scattered energies, not merely the background-corrected fluorescence.

Likewise, step c of claim 19 is incomplete and indefinite.

Step d of claim 23 also does not make clear that the detected signal minus the scattered/reflected and background energies is the value which is correlated with spore/non-viable bacteria mass/amount/numbers.

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Independent claims should begin with "A", while dependent claims should begin with "The".

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,760,406 [IDS] or US 5,968,766 [IDS].

The claims are directed to a method for the detection of microbes comprising:
exciting at least one intrinsic microbial fluorophore with fluorescence emission wavelength above 200 nm to emit fluorescence,
detecting the fluorescence signals including the minima and maxima of the excited fluorophores,
subtracting the reflected and scattered excitation and background energies from the detected signals, whereby the enumeration of microbes is determined by the magnitude of the detected fluorescence.

The references are relied upon as explained below.

US 5,760,406 discloses a method of detecting microbes on a non-living surface comprising:
exciting at least one intrinsic microbial fluorophore (NADH molecules) with a wavelength greater than 350nm,
detecting the fluorescence signals and the reflected or scattered energies (col. 2, l. 14, col. 4, l. 37), whereby the microbes are enumerated (claim 7).

US 5,968,766 has essentially the same disclosure as '406.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be

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obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill *et al.* [U].

The claims are directed to a method for the detection of microbes comprising:
exciting at least one intrinsic microbial fluorophore with fluorescence emission wavelength above 200 nm to emit fluorescence,
detecting the fluorescence signals including the minima and maxima of the excited fluorophores,
subtracting the reflected and scattered excitation and background energies from the detected signals, whereby the enumeration of microbes is determined by the magnitude of the detected fluorescence.

The references are relied upon as explained below.

Hill *et al.* disclose a method of detecting microbes comprising exciting an intrinsic fluorophore (tryptophan) with a He-Cd laser @ 325nm with an emission maxima @ 375nm (page 113). The magnitude of the detected fluorescence can be correlated to the number of microbes (biomass determination, page 108). The reflected/scattered excitation energy does not present a problem and is, in fact, zero (page 113). Therefore, it does not have to be subtracted from the fluorescence signal. It would be obvious to use this method whether the microbes are viable or nonviable because it is the tryptophan which fluoresces and is the basis for the quantitation of the microbes and the tryptophan would be present in the microbe whether the microbe were viable or non-viable.

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One of ordinary skill in the art would have been motivated at the time of invention to make this measurement in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to be 'JS' with a stylized flourish extending to the right.

Sandra Saucier
Primary Examiner
Art Unit 1651
April 11, 2003